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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,493	11/17/1999	JAMES MARTIN LENHARD	PU3571US	4399

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EXAMINER

ZEMAN, ROBERT

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/441,493

Applicant(s)

LENHARD ET AL.

Examiner

Robert A Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The amendment and response filed on 3-25-02 is acknowledged. Claims 13-16 have been added. Claims 1-8 remain withdrawn from consideration. Claims 9-16 are pending and currently under examination.

This application contains claims 1-8 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejection Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining the temperature of internal tissues or organs comprising replacing a portion of skin in a region of the body in proximity to the tissue or organ with a infrared-invisible polymer and measuring said temperature using infrared thermography **in mice and rats**, does not reasonably provide enablement for methods of determining the temperature of internal tissues or organs comprising replacing a portion of skin in a region of the body in proximity to the tissue or organ with a infrared-invisible polymer and

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measuring said temperature using infrared thermography **in any subject other than mice or rats** is maintained for reasons of record.

Applicant argues:

1. People of ordinary skill in the art would be able without undue experimentation how to prepare test animals across the spectrum of available test animals.
2. Persons of ordinary skill in the art will readily appreciate that the area of skin to be surgically excised and its proximity to the internal organ or tissue of interest will be analogous to the area and proximity of skin otherwise prepared by pre-scanning protocols such as simple shaving which is done to other radiographic procedures.

Applicant's arguments have been fully considered and deemed non-persuasive.

It is noted that a limitation upon which applicant relies (i.e., subjects are test animals) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, contrary to Applicant's assertion, it would not be "readily appreciated that the area of skin to be surgically excised and its proximity to the internal organ or tissue of interest will be analogous to the area and proximity of skin otherwise prepared by pre-scanning protocols such as simple shaving which is done to other radiographic procedures". The specification provides no guidance as to the area of skin that must be replaced relative to the size of the subject, whether said area is dependent on the physical characteristics (i.e. size, percent body fat, presence of fur etc.) of the subject or the effect of bone, cartilage, and muscle mass on

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infrared thermography. Additionally, the specification is silent on the effect adipose tissue; cartilage, muscle and bone have on the required “proximity” of the replacement site to the tissue/organ of interest. Consequently, one of skill in the art would not be able to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “portion” is maintained for reasons of record. Applicant argues that it would be obvious to one of skill in the art what is meant by said term. However, contrary to Applicant’s assertion, it is still unclear what area of skin must be replaced. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “proximity” is maintained for reasons of record. Applicant argues that it would be obvious to one of skill in the art what is meant by said term. However, contrary to Applicant’s assertion, it is still unclear how close to the tissue/organ must the replacement area be. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “wherein a difference in temperature resulting from the administration of a test agent indicates that the test agent had a thermodynamic effect” is

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maintained for reasons of record. Contrary to Applicant's assertion it would not be obvious to one of skill in the art whether it is the act of administering said agent or the biological effect of the test agent causes the change in temperature.

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "one or more dosages of the test agent" is maintained for reasons of record. . Contrary to Applicant's assertion it would not be obvious to one of skill in the art whether said dosages are administered simultaneously or over time.

Claim Rejections Withdrawn

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "before and after the administration of a test agent" is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "measured at one or more time points after administration of test agent" is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rendered vague and indefinite by the use of the phrase "removal of mouse skin". Is the entire mouse skin removed or just a portion thereof? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 14 is rendered vague and indefinite by the use of the phrase "wherein a difference in temperature resulting from the administration of a test agent indicates that the test agent had a thermodynamic effect". As stated previously in the rejection of claim 10 it would not be obvious to one of skill in the art whether it is the act of administering said agent or the biological effect of the test agent causes the change in temperature.

Claim 15 is rendered vague and indefinite by the phrase "one or more dosages of the test agent". As stated previously in the rejection of claim 11 it would not be obvious to one of skill in the art whether said dosages are administered simultaneously or over time.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
May 16, 2002


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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